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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO. ¹
10/625,357	07/23/2003	Ryland F. Young	HO-P01886US2	8574

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,357	Applicant(s) YOUNG ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U. S.C. 121:

- I. Claims 1-12, drawn to a method of screening for a sequence that encodes a target polypeptide for a lysis polypeptide, classified in class 435, subclass 4.
- II. Claims 13-21, drawn to a method of screening for a bacteriophage lysis polypeptide, classified in class 435, subclass 5.
- III. Claims 22-25, drawn to a method of screening for nucleic acid sequences from a library of sequences in a vector, classified in class 435, subclass 6.
- IV. Claims 26-29, drawn to a method of screening for bacteriophage with enhanced lytic activity, classified in class 324, subclass 5.
- V. Claims 34, 35, 37, 39, 41, 43, 45, 47, 49, and generic claims 30-32 to the extent that claims 30-32 read on this Group, drawn to a method of polypeptide antibiotic killing and to a polypeptide antibiotic with respect to the E protein and the MraY classified in class 530, subclasses 300 and 350.
- VI. Claims 33, 36, 38, 40, 42, 44, 46, 48, 50, and generic claims 30-32 to the extent that claims 30-32 read on this Group, drawn to a method of polypeptide antibiotic killing and to a polypeptide antibiotic with respect to the A2 protein and the MurA protein, classified in class 530, subclass 350.

It is noted that claims 30-32 are generic to Groups V and VI, and upon election of either of these Groups, claims 30-32 will be examined to the extent that they read on the elected Group.

Claims 30-32 link inventions of Groups V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 30-32. Upon

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the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other.

The methods of Groups I-IV are chemically, biologically, and functionally distinct from each other, and thus do not render each other obvious. The methods of Groups I-IV each comprises steps which are not present in or required for the other methods, and the effects of the methods are different. For example, the method of Group I requires a step of contacting bacteria with a lysis polypeptide and mapping a candidate bacterial sequence, and the effect of the method is to identify a target polypeptide which is a bacterial polypeptide. The method of Group II requires a step of screening a panel of recombinant bacterial strains, and the effect of the

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method is to identify a bacteriophage lysis polypeptide. The method of Group III requires the step of obtaining a library of DNA sequences in a plasmid expression vector, and the effect of the method is to identify a sequence encoding a lysis polypeptide. The method of Group IV requires a step of obtaining a bacterial strain transformed with a vector encoding a target polypeptide and a step of screening candidate bacteriophage, and the effect of the method is to identify phage with enhanced lytic activity.

The methods of Groups I-IV are biologically and functionally distinct from the methods of Groups V and VI, and thus the methods of Groups I-IV do not render obvious the methods of Groups V and VI. The methods of (Groups I-IV comprise steps which are not present in or required for the methods of Groups V and VI, and the effects of the methods are different. The methods of Groups I-IV are all screening methods, and thus they require steps using biological entities of unknown activity in the assay, for the purpose of screening for the desired effects. The effects of screening methods are the identification of a target, a lysis polypeptide, a gene, or a bacteriophage that was not previously known or that has a previously unknown or newly-made property. The methods of Groups V and VI comprise antibiotic killing, and thus require the use of a polypeptide that was already known to have antibiotic killing function. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups I-IV are unrelated to the products (polypeptide antibiotics) of inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions

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I-IV do not use the products of inventions V and VI, and the methods are not required to make the products of Inventions V and VI.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01) In the instant case the different inventions comprise structurally and functionally different polypeptides: the polypeptide antibiotics in the different groups are structurally and functionally distinct, and their target polypeptides are structurally and functionally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Since the search for one Group would not be coextensive with the search for another Group, it would be a burden to examine the Groups together.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter

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whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Jsk
June 21, 2006



JAMES KETTER
PRIMARY EXAMINER